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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,437	12/17/2001	Stephen A. Johnston	UTSD:736US/MBW	2358

7590 02/12/2004

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EXAMINER

FORD, VANESSA L

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 02/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/023,437	Applicant(s) JOHNSTON ET AL.	
	Examiner Vanessa L. Ford	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-73 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-73 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>2/3/04</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Election/Restriction

1. A new restriction requirement is set forth because of an omission of claims 52-61 in the restriction requirement mailed October 2, 2003. The restriction requirement mailed October 2, 2003 has been vacated. The Office apologizes for the oversight:

The new restriction requirement follows:

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I Claims 1-19 are drawn to a vaccine comprising a pharmaceutically acceptable carrier and at least one polynucleotide having a *Chlamydia* sequence, classified in class 536, subclass 23.1.

Further election of a single sequence is required.

Group II Claims 20-24 are drawn to a vaccine comprising a pharmaceutically acceptable carrier and at least one *Chlamydia* antigen, classified in class 530, subclass 300. Further election of a single sequence is required.

Group III Claims 25-61 are drawn to a method of immunizing, classified in class 424, subclass 263.1. Further election of a single sequence is required.

Group IV Claims 62-64 are drawn to a method of making antigens, classified in class 435, subclass 69.3.

Group V Claim 65 is drawn to a method of making antibodies, classified in class 424, subclass 184.1.

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- Group VI Claims 66-71 are drawn to a method of assaying for the presence of *Chlamydia* infection, classified in class 435, subclass 7.36. Further election of a single sequence is required.
- Group VII Claim 72 is drawn to a kit comprising a pharmaceutically acceptable carrier and an antibody direct against a *Chlamydia* antigen, classified in class 424, subclass 130.1.
- Group VIII Claims 73 is drawn to a method of testing for antigens, classified in class 435, subclass 7.1.

3. Groups I, II and VII are different products. The inventions are patentably distinct, each from the other, because they are different structurally and functionally.

4. Groups (I and II) and (III and VIII) are product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a material different process of using that product (MPEP 806.05(h)). In the instant case the antigen of Group II may be used for a number of different processes that are very much unrelated. For example, the polynucleotide of Group I can be used in hybridization assays.

5. Groups I and (IV and V) are unrelated as product and method of making. The product of Group I is not required for the methods of Groups (IV and V).

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6. Groups I and VI are unrelated as product and method of using. The product of Group I is not required for the method of Group VI.

7. Groups II and IV are product and process of making. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a material different process of using that product (MPEP 806.05(h)). In the instant case the antigen of Group II can be made synthetically.

8. Groups II and (V and VI) are unrelated as product and method of using. The product of Group II is not required for the methods of Groups (V and VI).

9. Groups III, IV, V, VI and VIII are different methods. They differ because they have different goals, require different method steps and parameters.

10. Groups VII and (III, IV and VIII) are unrelated as product and method of using. The product of Group VII is not required for the methods of Groups (III, IV and VIII).

11. Groups VII and V are product and process of making. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a material different process of using that product (MPEP 806.05(h)). In the instant case the method of making antibodies can be used to make materially different antibodies.

12. Groups VII and VI are product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a material different process of using that product (MPEP 806.05(h)). In the instant case the antigen of Group II may be used for a number of different processes that are very much unrelated. For example, the antibody of Group I can be used in affinity assays.

13. A. In the event applicant elects Group I, claims 1-19 applicant is required to elect a single sequence. Claims 1-19 recite distinct sequences based on structural differences and are patentably distinct one from another.

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B. In the event that applicant elects Group II, claims 20-24 applicant is required to elect a sequence. Claims 20-24 recite distinct SEQ ID Nos., based on structural differences patentably distinct one from another.

C. In the event that applicant elects Group III, claims 25-61 applicant is required to elect a single sequence. Claims 25-61 recite distinct SEQ ID Nos., based on structural differences patentably distinct one from another.

D. In the event that applicant elects Group VI, claims 66-71 applicant is required to elect a single sequence. Claims 66-71 recite distinct SEQ ID Nos., based on structural differences patentably distinct one from another.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

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Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

14. Because these inventions are distinct for the reasons given and have acquired a separate status in the art because of their recognized divergent subject matter as shown by their different classification, restriction for examination purposes as indicated is proper. Moreover, in the absence of restriction it would place an undue search and examination burden on the examiner.

15. Applicant is advised that the reply to this requirement to be complete must include an election of invention to be examined even though the requirement be traversed (37 CFR 1.143).

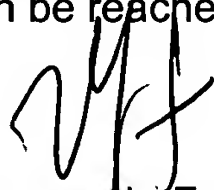
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16. Applicant is reminded that upon that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

17. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (703) 308-4735. The examiner can normally be reached on Monday – Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.



Vanessa L. Ford
Biotechnology Patent Examiner
February 5, 2004


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